

AMENDMENT NO. 1 AUGUST 2017
TO
IS 5395 (PART 1) : 1989 SPECIFICATION FOR SURGICAL IMPLANTS —
INTRAMEDULLARY NAILINGSYSTEMS FOR BONE SURGERY

PART 1 INTRAMEDULLARY NAILS WITH CLOVERLEAF OR V-SHAPED CROSS-SECTION

(Second Revision)

(Page 1, National Foreword, Cross References, Informal Table) — Substitute the following for the existing:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 5832/1 : 1987 Implants for surgery — Part 1 : Wrought stainless steel	IS 5347 (Part 2) : 1983 Requirements for orthopaedic implants : Part 2 Wrought stainless steel (<i>first revision</i>)	Identical
ISO 5832-5 : 2005 Implant for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten- nickel alloy	IS/ISO 5832-5 : 2005 Implant for surgery — Metallic materials : Part 5Wrought cobalt-chromium-tungsten- nickel alloy	- do -

(Page 1, National Foreword) — Insert the following at the end:

The product shall be clearly and indelibly marked suitably with the following:

- a) Name and trade-mark of the manufacturers; and
- b) Type, size/diameter of nails/hooks

This standard also makes a reference to the BIS Certification Marking of the product. The details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.